REMARKS/ARGUMENTS

As a result of this Amendment, claims 1-16 are under active consideration in the subject patent application.

In the Official Action, the Examiner has:

(1) rejected claims 2 and 3 under 35 U.S.C. §112, second paragraph;

(2) rejected claims 1 and 9 under 35 U.S.C. §101;

(3) rejected claims 1-16 under 35 U.S.C. §103(a), in view of a combination of U.S. Patent No. 6,370,511, issued to Dang and U.S. Patent No. 6,277,071, issued to Hennessy et al.; and

(4) stated that the prior art made of record and not relied upon is considered pertinent to Applicant's disclosure.

With regard to Items 1 and 2, Applicant has amended claims 1, 2, and 3 so as to more clearly provide antecedent basis by clarifying that the gathering of patient care data includes applying a risk assessment tool that comprises a rating scale to objectively characterize the subjective condition of the patient's skin and wound. In addition, claim 5 has been amended so as to correct an inadvertent typographical error. Claim 10 has been amended to clarify that information created by practice of the method of the invention is stored in a data record.

Applicant respectfully submits that proper antecedent basis for all of the limitations in claims 2 and 3 has been provided as a result of this change to the

claims. Reconsideration and withdrawal of the rejection of claims 2 and 3 under 35 U.S.C. §112, second paragraph, are requested.

Claims 1, 9, 10, and 15 have been amended so as to clearly point out the statutory subject matter claimed by Applicant as her invention. More particularly, Applicant has amended claims 1, 9, 10, and 15 so as to more clearly define that the method of the present invention provides a clinician with a notification of a variation from accepted clinical pathways established for the proper treatment of a skin wound at the time of performance of the clinical action identified as a variance. The determination of a variance from an identified clinical pathway, and the production and immediate issuance of an alert notice are both useful and tangible results of the practice of the method defined by claims 1, 9, 10, and 15. Applicant respectfully submits that these results are sufficiently "*concrete*" to come within the scope of the Federal Circuit's holding that a process for the transformation of data must yield ". . . *a useful, concrete, and tangible result* . . .," State Street Bank & Trust Co. v. Signature Financial Group, Inc., 149 F.3d 1368, 1373, 47 USPQ 2d 1596, 1601 (Fed. Cir. 1998). Reconsideration and withdrawal of the rejection of claims 1 and 9 under 35 U.S.C. §101, are requested.

With regard to Item 3; Applicant respectfully traverses the Examiner's proposed combination of U.S. Patent No. 6,370,511, (the "Dang reference") with U.S. Patent No. 6,277,071, (the" Hennessy reference") and requests reconsideration and withdrawal of the rejection of claims 1-16 under 35 U.S.C. §103 for the following reasons.

In order for a *prima facie* case of obviousness to be established, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings, and the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP §2142. Applicant further respectfully submits that it is the invention as a whole, i.e., the structure, its properties, and the problem it solves, that must be considered in making a determination of obviousness. In re Shaffer, 108 USPQ 326, In re Wright, 6 USPQ2d 1959. Also, the motivation to combine references cannot come from the invention itself. In re Oetiker, 24 U.S.P.Q. 2d 1443, 1446. The Examiner has not satisfied any of these requirements, and therefore has failed to establish a *prima facie* case of obviousness.

More particularly, Applicant has discovered a process for accessing and documenting wound and skin conditions that includes an automatically triggered alerting mechanism that is activated, in real time, when a treatment is initiated by a treating physician that deviates from an expected or standard treatment under the current clinical circumstances. Neither Dang nor Hennessy alone or in any valid combination provide such a methodology.

Dang discloses a method for profiling medical claims to assist health care managers in determining the cost-efficiency and service quality of health care providers. Dang suggests that his method allows an objective means for measuring and quantifying health care services. In other words, Dang provides a

retrospective study of insurance claims, and is not interested, at all, in patient diagnosis or real time treatment of patients at bed side. Instead, Dang provides a cost benefit analysis and variant analysis to optimize pay-out for medical claims. The problem being solved and the methodology being taught by Dang is simply not the same, or even vaguely suggestive of Applicant's method for assessing deviations from a pre-selected medical treatment that has been indicated by appropriate diagnosis from a clinician, at the time of performance of the clinical action identified as a variance.

The Examiner admits that Dang does not explicitly disclose monitoring the recorded clinical actions taken by a clinician to determine variations from an identified clinical pathway or, alerting a clinician of a variance from the identified clinical pathway. This should not be surprising since Dang's method is applied to data the is significantly removed in time and place from the clinician and her patient! Moreover, Dang utterly fails to suggest in any way that an alert notice be provided to a clinician at the time of performance of a clinical action that has been identified as a variance from the appropriate clinical pathway. This is because, Dang's method operates on data that is "retrospective" in nature. In other words, information that has been gleaned from data records of episode treatment groups that are used to define the basic analytical unit in the computer-implemented method of Dang's invention (col. 9, lines 20 – 24). At Column 9, lines 36 – 40, Dang states that his medical claims profiling system utilizes episode treatment groups that vary depending upon the definition of specificity of

the health care management organizations that input the data. Accordingly, Dang could not possibly suggest the monitoring or identification of variances, at the time of performance of the clinical actions, since all clinical actions dealing with a particular patient would have already occurred in the past, and been paid for by an insurance company, before the data is ever provided to Dang's system. Thus, Dang fails to suggest or provide the requisite motivation to one having ordinary skill in the art to provide a method for accessing deviations from a pre-selected medical treatment that has been indicated by an appropriate diagnosis.

The Examiner relies upon the Hennessy reference to provide the missing teachings to Dang in support of the proposed combination. Applicant respectfully submits that Hennessy utterly fails to provide those missing teachings, or combined with Dang, to provide the requisite motivation to one of ordinary skill in the art to combine the references as the Examiner has suggested, absent impermissible hindsight.

The Hennessy reference appears to disclose a system for monitoring diabetes including a data base for storing a plurality of patient data entries and means for sorting the patient data entries according to whether a test threshold has been crossed. Hennessy states that the invention provides a data processing system and method for managing diabetes care which utilizes known medical standards adopted by the American Diabetes Association, among others, to customize a treatment plan which can interface with a physician, health care plan and patient. (Col. 3, lines 65 – 67; Col. 4, lines 1 – 7). Thus,

Hennessy discloses a planning process that includes a set of criteria which define a high risk patient. Unlike Applicant's method, these criteria are not clinical pathways for treatment of a chronic condition, in real time. Instead, Hennessy's system continually monitors the patient, setting forth alarms when the patient fails to receive a planned examination or service or the examination does not fall within an expected range. However, Hennessy's method does not disclose or suggest, in anyway, the issuance of an alert notice for deviations from a standard course of treatment according to an accepted clinical pathway, at the time of performance of the clinical action.

In other words, Hennessy's system provides a patient with information about their condition or current treatment needs, and allows them to plan, prospectively, for prevention activities, i.e., clinical exams and patient services. It only generates alerts to a medical provider or the patient if a test is not performed as planned, and also if the test results do not fall within the expected range (col. 1, lines 26 – 30). In essence, Hennessy provides a managed care system for informing a patient prospectively, and allows a patient to plan for treatment of their chronic disease. Significantly, and unlike the method of the present invention, none of the results of Hennessy's method provide information to the patient in "real time", i.e., at the time that a clinician initiates a clinical action and treatment of a malady.

Taken as a whole, Dang and Hennessy teach methods for utilizing healthcare insurance related data and clinician provided data, either

retrospectively (Dang) or prospectively (Hennessy) to evaluate the cost efficiency, efficiency of past treatment, and to allow for planning for future treatment. Neither reference alone, nor their combination evenly vaguely suggests an automatically triggered alerting mechanism that is activated, in real time, during consultation at bedside, when a treatment is initiated by a treating physician that deviates from an expected or standard treatment. Furthermore, the requisite motivation to combine these references is absent from them.

Since nothing in the prior art references would lead a person of ordinary skill in the art to formulate a method like that described in the application, or defined by claims 1 - 16, it appears that hindsight knowledge of the present invention is the only motivation to combine these references. It is improper to use the claims as a framework with individual parts of separate prior art references employed to recreate a facsimile of the claimed invention. See, W.L. Gore and Associates, Inc. v. Garlock, Inc., 220 U.S.P.Q. 303, 312. The Examiner is also referred to In re Bond, 910 F2d 831, 15 U.S.P.Q. 2d 1566 (Fed. Cir. 1990) which held that the PTO erred in rejecting a claimed invention as an obvious combination of the teachings of two prior art references when the prior art provided no teaching, suggestion, or incentive supporting the combination. See also, Northern Telecom, Inc. v. Datapoint Corp., 15 U.S.P.Q. 2d 1321, 1323; In re Geiger, 2 U.S.P.Q. 2d 1276, 1278. The Examiner is further referred to Smithkline Diagnostics, Inc. v. Helena Laboratories Corp., 859 F2d 878, 887, 8 U.S.P.Q. 2d 1468, 1475 (Fed. Cir. 1988) which held that one "cannot pick and

choose among the individual elements of assorted prior art references to recreate the claimed invention." .

In summary, Applicant submits that the unique method defined by claims 1 - 16 is not disclosed in the prior art references, taken as a whole, and there is no teaching or suggestion in the references to support their use in the particular claimed combination, or to motivate a person of ordinary skill to seek out such a combination. In the absence of such, the references are improperly combined. In any event, claims 1 - 16 define over the combination of Dang and Hennessey.

In view of the foregoing, Applicant respectfully submits that claims 1 - 16 are in condition for allowance. Favorable reconsideration is therefore respectfully requested.

If a telephone conference would be of assistance in advancing prosecution of the above-identified application, Applicant's undersigned Attorney invites the Examiner to telephone him at **717-237-5516**.

Respectfully Submitted,

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